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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,946	08/22/2001	Charles Chauveau	C1190/20008	5350

7590 10/16/2003

Caesar Rivise Bernstein  
Cohen & Pokotilow  
Seven Penn Center 12th Floor  
1635 Market Street  
Philadelphia, PA 19103-2212

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/16/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,946

Applicant(s)

CHAUVEAU ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 48-53 and 55-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-53 and 55-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt of extension of Time, Amendment E, and Rule 132 Declaration received on July 28, 2003 is acknowledged. Claims 48-53, and 55-74 are pending in this application.

#### ***Response to Amendment***

Applicant's Amendment E, filed July 28, 2003, overcomes rejection of claims 48-50, 53, 55-56, 59-63, 65, 67-70, and 73-74 under 35 U.S.C. 102(e) as being anticipated by Gowan (5,876,759).

The Rule 132 Declaration under 37 CFR 1.132 filed July 28, 2003 is sufficient to overcome the Gowan as an anticipatory reference.

However, it should be noted that applicant argues that Gowan's tablets have different properties such as hardness and tablet diameter. The examiner points out that these features are not limitations in the instant claims and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 48-53 and 55-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (6,465,009) in view of Ku et al (5,994,348).**

Liu et al teach a rapidly disintegrating tablet in about 1 to 40 seconds (col. 2, lines 45-51). Liu teaches a formulation containing a coated active such as ibuprofen and acetaminophen (up to 50%; exemplified 8.7%), a binder (0.5-5%), at least one lubricant such as magnesium stearate (0.5-1%), and fillers (mannitol, xylitol) (40-99%). See column 3, lines 5-15, column 7, lines 5-20, and examples. Liu et al teach croscarmellose sodium as an additional disintegrant. See column 7, lines 64-68. Sweetening agents such as aspartame are taught on column 8. Liu teaches lubricants help in manufacturing of the tablet such as helping prevent the ejection sticking of the compressed formulation to the pressing dies and sticking. See column 7, lines 60-64.

Liu et al does not teach inclusion of a permeabilizing agent.

Ku et al teach a pharmaceutical composition with excellent wetting, disintegration, and rapid release properties (col. 2, lines 5-15). Ku teaches the use of anti-adherents such as .25-5% silicon dioxide reduce the stickiness of the formulation and prevent adherence to metal surfaces. (col. 4, lines 20-30). Further, Ku teaches the combination of magnesium stearate and silicon dioxide provides a superior lubrication effect while minimizing any decline in tablet dissolution performance (col. 5, lines 59-65).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Liu et al and Ku et al and to look to Ku et al and include silicon dioxide in the composition. One would be motivated to do so since Ku teaches the advantages of using an anti-adherent agent in reducing the stickiness of the composition and Lu teaches the problem of "ejection sticking". Further, one would expect similar results since Ku teaches the combination of magnesium stearate, a lubricant utilized by Liu, and silicon dioxide provide for an excellent lubricating effect.

### ***Response to Arguments***

Applicant argues that Liu et al teach a non-saccharide water-soluble binder such as PVP in order to increase disintegration. It is argued that the amount of disintegrating agent is not taught or a permeabilizing agents. Applicant argues that Ku et al is intended to be swallowed and not disintegration in the oral cavity. Further, it is argued that Ku teaches the use of the anti-adherent to reduce stickiness of the active agent itself and Liu et al does not undergo this problem.

Applicant's arguments have been fully considered but they are not persuasive. First the examiner points out that the claim language does not exclude other ingredients such as PVP in the composition. As recognized by the applicant, PVP used in the amount of 0.5-5% acts as a disintegrating agent in Liu et al. Note column 6, line 35. Further, Liu clearly states that another disintegrating agents such as croscarmellose may be used other than PVP. Therefore, one would be motivated to use croscarmellose in the same amount as PVP since both have the same function in the composition. The

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examiner points out that Ku et al teach the use of instant disintegrants in the instant amount.

In regards to the argument that Liu et al does not teach the permeabilizing agent, the examiner points out the secondary reference is relied upon to overcome this deficiency. Ku et al is relied upon to teach the permeabilizing agent and not for the broad teaching of the instant invention. Therefore, Ku does not have to teach all the limitations of the instant invention, i.e. buccal disintegration, since this is not Liu's deficiency. It is well known to use anti-adherents in the art despite the time of formulation of rapid versus sustained since anti-adherents are utilized to solve tablet manufacturing problems and not disintegration problems. Therefore, a motivation to use an anti-adherent still exists in Liu. Further, the examiner points to column 7, lines 60-64 where Liu teaches that lubricants help in manufacturing of the tablet and help prevent the ejection sticking of the compressed formulation to the pressing dies and sticking and Ku teaches the combination of silicon dioxide and magnesium stearate have an excellent lubricating effect. See column 7, lines 60-64 and Table 1. Therefore, clearly the "sticking" problem exists in Liu et al. Thus, clearly there is a motivation to use an anti-adherent agent.

**Claims 48-53, 55-56, 59-70, and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augello et al (6,099,865) in view of Gergely et al (4,832,956) or in view of Myers et al (5,567,439).**

Augello et al teach a rapid disintegrating composition containing a croscarmellose coated active particles. The croscarmellose coating material is utilized in

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the range of 10-50 percent and has a dual purpose of making the active and acting as a super disintegrant. See column 2, lines 41-65. When the croscarmellose is incorporated into the final composition, it is used in the amount of 1-10%. See column 4, lines 48-52. The actives that are suitable include acetaminophen and ibuprofen. See column 4, line 25. Sweeteners such as aspartame and granular mannitol in instant amounts (46%) are taught. See examples. The composition includes 0.82% magnesium stearate.

Disintegration rates of 30 and 50 seconds are taught in the examples.

Augello et al do not teach the permeabilizing agent.

Gergely et al teach a rapidly disintegrating tablet. Gergely teaches finely dispersed silica (aerosil) is an excellent disintegrating agent. See column 1, lines 23-27.

Meyers et al teach glidants such as silica compounds are useful in tableting since they enhance flow properties by reducing interparticle friction. Furthermore, silicate is used as a disintegrant to enhance the dispersibility of compressed tablets in aqueous environments. See column 13, lines 55-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Augello et al and Gergely et al/Meyers et al and utilize silica for its dual purpose. One would be motivated to do so since Gergely, who also teaches a rapidly disintegrating tablet, teaches silica is an excellent disintegrant. Further, Meyers teaches silica compound are not only useful as disintegrants but also as glidants in the tableting process. Therefore, one would be motivated to add silica to increase the rate of disintegration since adding silica would have an obvious additive effect with the disintegrant croscarmellose since both have the

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same function in the composition. Additional motivation is to enhance flow properties when tableting the formulation.

**Claims 48-53 and 55-74 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Augello et al (6,099,865)**

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

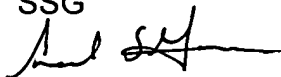


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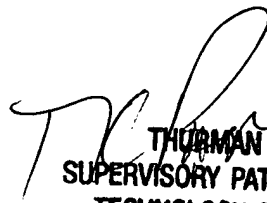
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



10/3/03



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600